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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,315	03/30/2004	Mechthild Rieping	7909/81000	1764
7590 06/12/2007 Michael A. Sanzo Fitch, Even, Tabin & Flannery			EXAMINER	
			KIM, ALEXANDER D	
Suite 401L, 1801 K Street, N.W. Washington, DC 20006-1201		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

1		Application No.	Applicant(s)			
Office Action Summary		10/812,315	RIEPING, MECHTHILD			
		Examiner	Art Unit			
		Alexander D. Kim	1656			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
 Responsive to communication(s) filed on <u>20 March 2007</u>. This action is FINAL. 2b) ☐ This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 						
Disposition of Claims						
 4) Claim(s) 13-36 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 20-26 is/are rejected. 7) Claim(s) 13-19 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 						
Priority u	ınder 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
2) Notice 3) Information	t(s) te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) tr No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	Pate			

DETAILED ACTION

Application Status

1. In response to the previous Office actions, a non-Final rejection (mailed on 12/13/2006), Applicants filed a response and amendment received on 03/20/2007. Said amendment cancelled Claims 1-12, amended Claims 13, 15, 17-18 and 22, added new Claims 23-26. Thus, Claims 13-26 are pending in the instant Office action.

Withdrawn-Claim Objections

2. The previous objection of Claim 13 is withdrawn by the virtue of Applicant's amendment.

New-Claim Objections

- 3. Claims 13 and 23 are objected to because of the following informalities: Claims 13 and 23 recites "said bacterium is of the Enterobacteriaceae" (emphasis added). The terms "of the" should be ---an--- for better format of the claims. Appropriate correction by removing underline is required.
- 4. Claims 15 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim 13. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

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In the instant case, the Claim 15 recites the limitation of SEQ ID NO: 3 for the nucleotide sequence and the Claim 17 recites the limitation of said overexpression by increasing the coy number of said DNA, which is identical to the scope of its independent claim (Claim 13). Appropriate correction is required.

- 5. Claim 23 is objected to because of the following informalities: Claim 23 has "," (comma) between "starch" and "cellulose" with underline. Appropriate correction by removing underline is required.
- 6. Claims 14, 16 and 18-19 are objected to because they are dependent from an objected Claim 13.

Withdrawn-Claim Rejections - 35 USC § 112

- 7. The previous rejection of Claims 13-22 under 35 U.S.C. 112, second paragraph, for reciting the limitation "overexpressed" is withdrawn by the virtue of Applicant's amendment.
- 8. The previous rejection of Claim 21 under 35 U.S.C. 112, second paragraph, for reciting the limitation "overexpresses" is withdrawn by the virtue of Applicant's amendment.

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9. The previous rejection of Claim 22 under 35 U.S.C. 112, second paragraph, reciting the limitation "expression reduced" is withdrawn by the virtue of Applicant's amendment.

- 10. The previous rejection of Claims 13-16 and 18-22 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by the virtue of Applicant's amendment.
- 11. The previous rejection of Claims 13-16 and 18-22 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by the virtue of Applicant's amendment.

Maintained-Claim Rejections - 35 USC § 112

12. The previous rejection of Claims 21 and 22 under of 35 U.S.C. 112, second paragraph, for reciting the limitation "the thrABC operon" or "the tdh gene" (emphasis added) is maintained.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues "the claims are interpreted based upon their use in the specification" and "there is never a suggestion that the invention includes anything broader than these specific gene" (see Remarks, middle of page 9). However, a disclosure of contradicting the statement above reciting the "genes encompassed by the claims that, under the doctrine of equivalents, would be considered substantially the

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same" (see Remarks, middle of page 9). The scope of claims is unclear according to the instant contradicting argument.

"While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not itself impose that limitation. A broad interpretation of a claim by USPTO personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim." (see MPEP, 2106 [R-5], II-C).

As noted in the previous office action, there is insufficient antecedent basis for this limitation in the claim. It is unclear if the claims are limited to the one species disclosed in the specification (see pages 12-15) or to any gene from other organism.

New-Claim Rejections - 35 USC § 112

13. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, enabling deposit, as failing to comply with the enablement requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological material, specifically the host cells recited in Claim 25. Since the biological material are essential to such an invention they must be obtainable by a repeatable method set forth in the specification or

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otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 USC 112 §1st may be satisfied by a deposit of the biological materials.

This Office action reminds applicants that an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific of record over his or her signature and registration number, stating that the specific biological materials will be irrevocable and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Applicant's attentions is directed to MPEP section 2400 in general, and specifically to 2411.05, as well as to 37 CFR 1.809(d), wherein it is et forth that "the specification shall contain the accession number for the deposit, the date of the deposit, "the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

Withdrawn-Claim Rejections - 35 USC § 102

The previous rejection of Claims 13-14 and 17-20 under 35 U.S.C. 102(b) as 14. being anticipated by Valle et al. as evidenced by Blattner et al. is withdrawn by the virtue of Applicant's amendment.

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15. The previous rejection of Claims 13-14 and 17-20 under 35 U.S.C. 102(a) as being anticipated by Hernandez-Montalvo et al. as evidenced by Blattner et al. and Lee et al. is withdrawn by the virtue of Applicant's amendment

Maintained-Claim Rejections - 35 USC § 102

16. Claims 23-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Valle et al. (USPAP 2002/0155521 published on Oct. 24, 2002, as cited in the previous Office Action) as evidenced by Blattner et al. (1997, Science 277:1453-1474, as cited in the IDS).

The rejection was stated in the previous office action as it applied to previous Claims 13-14 and 17-20. In response to this rejection, applicants have amended Claims 13 and 17-18 (Claims 14 and 19-20 dependent therefrom) and traverse the rejection as it applies to the newly amended claims.

Applicants argue the inclusion of the limitation reciting "a PEP-dependant phosphotransferase (pTS) pathway" is sufficient to overcome the rejection of claims under 35 USC§ 102. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. However, any glucose transporter in the bacteria of Valle et al. or Hernandiz-Montalvo et al. is encompassed by the term "PEP-dependent phosphotransferase pathway" by the broad and reasonable interpretation of the term in Claim 23. For the reasons above and the previous office action, the instant claims are rejected.

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17. Claims 23-24 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Hernandez-Montalvo et al. (2003 Sep. 20, Biotechnol Bioeng, Vol. 83, page 687-694) as evidenced by Blattner et al. (1997, Science 277:1453-1474, as cited in the IDS) and Lee et al. (2003, September, Journal of Bacteriology, vol. 185, p. 5442-5451). This rejection is necessitated by the amendment.

The rejection was stated in the previous office action as it applied to previous Claims 13-14 and 17-20. In response to this rejection, applicants have amended Claims 13 and 17-18 (Claims 14 and 19-20 dependent therefrom) and traverse the rejection as it applies to the newly amended claims.

Applicants argue the inclusion of the limitation reciting "a PEP-dependant phosphotransferase (pTS) pathway" is sufficient to overcome the rejection of claims under 35 USC§ 102. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. However, as noted above, any glucose transporter in the bacteria of Valle et al. or Hernandiz-Montalvo et al. is encompassed by the term "PEP-dependent phosphotransferase pathway" by the broad and reasonable interpretation of said term. For the reasons above and the previous office action, the instant claims are rejected.

Withdrawn-Claim Rejections - 35 USC § 103

18. The previous rejection of Claim 21 under 35 U.S.C. 103(a) as being unpatentable over Valle et al. (USPAP 2002/0155521 published on Oct. 24, 2002, as cited in the previous Office Action) in view of Debabov et al. (USP 6,132,999 published on Oct. 17,

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2000, as cited in the previous Office Action) is withdrawn by the virtue of Applicant's amendment.

19. The previous rejection of Claim 22 under 35 U.S.C. 103(a) as being unpatentable over Valle et al. (USPAP 2002/0155521 published on Oct. 24, 2002) in view of Debavov et al. (USP 5,705371 published on Jan. 6, 1998) is withdrawn by the virtue of Applicant's amendment.

Summary of Pending Issues

- 20. The following is a summary of the issues pending in the instant application:
 - a) Claims 13 and 23 are objected to because of the term "of the".
 - b) Claims 15 and 17 are objected because of improper dependent form for failing to further limit the subject matter of a previous claim 13.
 - c) Claim 23 is objected to because "," (comma) between the term "starch" and "cellulose" with underline.
 - d) Claims 14, 16 and 18-19 are objected to because they are dependent from an objected Claim 13.
 - e) Claims 21 and 22 under of 35 U.S.C. 112, second paragraph, for reciting the limitation "the thrABC operon" or "the tdh gene" is maintained.
 - f) Claim 25 is newly rejected under 35 U.S.C. 112, first paragraph, enabling deposit requirement.
 - g) Claims 23-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Valle et al. as evidenced by Blattner et al.
 - h) Claims 23-24 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Hernandez-Montalvo et al. as evidenced by Blattner et al. and Lee et al.

Conclusion

21. Claims 13-26 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim June 4, 2007

PRIMARY EXAMINER